REMARKS

Reconsideration of the application in view of the above amendments and following remarks is respectfully requested.

Claims 7-12 were pending in the subject application. Claim 10 has been cancelled without prejudice to pursue in a related application. Claim 12 has been amended to delete the phrase "having immunogenic properties" and to change the dependency from now cancelled claim 10. No new matter has been added to the claims. Therefore, claims 7-9, 11 and amended claim 12 are now pending in the subject application.

In the Office Action dated May 08, 2003, claims 10 and 12 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. In particular, the term "equivalent" in claim 10 was objected to. Claim 12 was rejected because it depended from rejected claim 10.

Applicants respectfully disagree that claim 10 was not definite within the meaning of Section 112, second paragraph. Nevertheless, in order to expedite allowance of the remaining pending claims, claim 10 has been cancelled without prejudice and claim 12 has been amended to not depend from claim 10. Accordingly, this rejection of claims 10 and 12 has been rendered moot.

Therefore, withdrawal of this rejection of claims 10 and 12 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

In the Office Action, claim 10 was objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form.

Applicants respectfully disagree. Nevertheless, as described above, claim 10 has been cancelled without prejudice. Accordingly, this objection to claim 10 has been rendered moot.

Therefore, withdrawal of this objection to claim 10 under 37 C.F.R. § 1.75(c) is respectfully requested.

In the Office Action, claims 10 and 12 were rejected under 35 U.S.C. § 112, first paragraph. In particular, the phrase "having immunogenic properties" in claim 12 was objected to in part (A) of the rejection. In part (B) of the rejection, the term "equivalent" in claim 10 was objected to (and claim 12, due to its former dependence from claim 10).

Applicants respectfully disagree with part (A) of the rejection. The subject specification contemplates fusion proteins wherein the additional peptide or polypeptide may or may not have immunogenic properties. The Office Action appears to be focused only on an illustrative embodiment. Since it is not necessary to require that the additional peptide or polypeptide under all circumstances have immunogenic properties, claim 12 has been amended as recited above to delete the phrase. The additional component is a peptide or polypeptide regardless of whether it does or does not have immunogenic properties. Regarding part (B) of the rejection, Applicants respectfully disagree and believe that it would be evident to one of ordinary skill in the art that the language of the subject specification and claim 10 is comparing the immune response of a variant to that of the polypeptide having SEQ ID NO:2. The immune response is intended to be the same or better ("at least an equivalent immune response"). Nevertheless, as described above, claim 10 has been cancelled herein.

Therefore, withdrawal of this rejection of claims 10 and 12 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

In the Office Action, claims 7-12 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter not enabled. In particular, as stated at page 5 of the Office Action, the claims are asserted to be "clearly intended to encompass methods of gene therapy". Applicants respectfully, but strenuously, traverse this rejection.

Claims 7, 8 and 9 are independent method claims and claims 11-12 depend (or in the case of claim 10 depended) directly from claims 7-9. The preamble of each of method claims 7-9 recites in part "eliciting or enhancing an immune response to HER-2/*neu* protein". This is the response recited in the body of each of claims 7-9 as "said response".

Claims 7-9 and 11-12 meet the enablement requirements of Section 112, first paragraph. The subject specification, especially when taken in combination with knowledge of the art at the time of the invention, taught one of ordinary skill in the art how to elicit or enhance an immune response to HER-2/*neu* protein with a nucleic acid molecule or viral vector as defined in claims 7-9. This is confirmed by a review of the subject application's prosecution history as summarized below. Even assuming that the subject claims can be interpreted to encompass "gene therapy", Applicants enabled the recited utility (i.e., "to elicit or enhance an

immune response to HER-2/*neu* protein") and therefore have satisfied the enablement requirement of Section 112, first paragraph.

A review of the subject application's prosecution history confirms that Applicants enabled the recited utility. (It is noted that the present Examiner has been the Examiner for the subject application beginning with issuance of the Restriction Requirement in Paper No. 9 to the present.) In Paper No. 13, claims 7-12 were rejected under Section 112, first paragraph, for lack of enablement. In Paper No. 17, claims 8-12 were rejected on new grounds under Section 112, first paragraph, for lack of enablement. There was no rejection of claim 7 under Section 112, first paragraph, in Paper No. 17. As stated in paragraph "5." of Paper No. 17, "All other rejections and objections as stated in Paper No. 13 are withdrawn." Therefore, claim 7 is enabled for the recited utility. In Paper No. 20, there was no rejection of claims 8-12 under Section 112, first paragraph. As stated in paragraph "5." of Paper No. 20, "All other rejections and objections as stated in Paper No. 17 are withdrawn." Therefore, claims 8-12 are enabled for the recited utility. In summary, rejections to claims 7-12 under 35 U.S.C. § 112, first paragraph, for lack of enablement of the recited utility were previously made and were overcome. Therefore, it is improper to reject these claims on the basis that the specification does not enable "gene therapy".

Although the above discussion is sufficient to overcome this rejection under Section 112, first paragraph, Applicants do not concede that any of the claims encompasses "gene therapy". At page 5 of the Office Action, it is asserted: "The claims are clearly intended to encompass methods of gene therapy." Applicants disagree. As discussed above, the pending claims are directed to "eliciting or enhancing an immune response to HER-2/*neu* protein." As stated at page 8, lines 27-30, of the subject application: "The disclosure of the present invention also shows, in another aspect, that nucleic acid molecules directing the expression of such a peptide may be used alone or in a viral vector for immunization." Immunization with DNA and viral vectors is <u>not</u> gene therapy. The purpose of gene therapy is to produce <u>sustained</u> expression of a protein (e.g., to replace its lack due to an absent or defective gene encoding the protein). Contrary to the purpose of gene therapy, the purpose of immunotherapy is to induce <u>transient</u> expression of a small amount of protein. Immune systems can recognize a very broad range of

antigens, from minute microgram quantities to gram quantities. At page 5 of the Office Action, Verma et al. (Nature 389:239-242, 1997), a reference provided by the Patent Office, is cited as teaching that an ongoing problem of gene therapy is an inability to obtain sustained expression. Therefore, whereas a lack of sustained expression is a problem for gene therapy, it is not a problem for immunotherapy.

Further, Applicants point out that Verma et al. supports Applicants' position that the claims do not encompass gene therapy. Verma et al. is entitled: "Gene Therapy - promises, problems and prospects". In the first paragraph at page 239 of Verma et al., it is stated in part: "But problems – such as … and host immune reactions – remain formidable challenges." Thus, it is clear from Verma et al. that "host immune reactions" are a problem to gene therapy. This is understandable, since the purpose of gene therapy is to produce sustained expression of a protein and a host immune response would interfere with the protein. Accordingly, if gene therapy is desired, then a host immune response is not desired. However, a host immune response is precisely to what the claims of the subject application are directed. As discussed above, independent claims 7-9 recite in part a "method for eliciting or enhancing an immune response" and the subject specification (at page 8, lines 27-30) states that one aspect of the present invention is the use of nucleic acid molecules alone or in a viral vector "for immunization." Therefore, if the pending claims are directed to what is characterized (in a reference cited in the Office Action) as one of the "problems" of gene therapy, it is respectfully submitted that the pending claims cannot encompass gene therapy. In conclusion, immunization with DNA or viral vectors is not gene therapy.

Therefore, Applicants believe that the rejection of claims 7-12 under 35 U.S.C. § 112, first paragraph, has been overcome. Withdrawal of this rejection is respectfully requested.

Therefore, in light of the amendments and remarks set forth above, Applicants believe all the Examiner's objections and rejections have been obviated or overcome, respectively. Reconsideration of the application and allowance of all now pending claims (7-9 and 11-12) are respectfully requested. If there is any further matter requiring attention prior to allowance of the subject application, the Examiner is respectfully requested to contact the undersigned attorney (at 206-622-4900) to resolve the matter.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

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